



The Center For Pain Management

Finally, A Solution For Your Pain
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Date: October 8, 2000

To: Dockets Management Branch (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir or Madam;

I'm writing in strong opposition to the FDA's intention to re-classify totally implantable spinal cord stimulators, from class III to class II. Such a move would eliminate some critical checks and balances that help promote patient safety. SCS devices are extremely complex; they involve highly intricate, and specialized circuitry, and a power source that is totally implantable with leads, surgically placed into the spinal area. The devices themselves are as complex as the procedure to implant them. I am deeply concerned that the potential re-classification of this device to class II opens the door to allow a lower standard of product in the market, which could potentially endanger the lives of patients. As a physician, who treats chronic pain patients on a regular basis, I am concerned for patient safety, as well as the integrity of my practice. Even with implantable SCS devices already approved by the FDA, not all safety features are well understood. To insure patient safety, it is critical that manufacturing checks be in place. I am fearful that lowering the rating to class II will allow manufacturers to place onto the market that spinal cord stimulator units that have not passed the highest level of quality assurance. I am compelled to note, that in 1995, the FDA itself deemed these devices potentially high risk. The fact that the agency is planning to down grade them is now a cause for great concern. I firmly believe that the re-classification of these devices compromises the integrity of the entire class, a misstep that will undoubtedly jeopardize future patients. The FDA classification level III with corresponding pre-market approval, is imperative to protecting the safety of patients receiving these complex technologically advanced devices.

Thank you for your careful consideration of my comments; please call me at (410) 383-7443, if I can provide you with additional information.

Sincerely,

Mark H. Coleman, MD

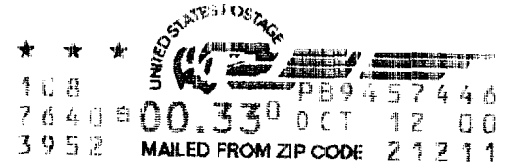
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